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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,223	04/20/2000	Gregory B. Williams	MN-9050	5050

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06/26/2002

EXAMINER

WEBER, JON P

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/26/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/553,223

Applicant(s)

WILLIAMS ET AL.

Examiner

Jon P. Weber, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-36 and 43-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-36 and 43-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, a response and Information Disclosure, filed on 18 April 2002 has been entered.

Claims 27-36 and 43-52 have been presented for examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

Claim 51 is objected to because of the following informalities: "microporicessor" is a misspelling. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 27-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 27-36 now depend from canceled claim 26. In view of the newly added claims 43-52, it is thought that it was intended to cancel claims 27-36, i.e. to cancel claims 22-36 not 22-26. These claims are not further examinable.

Claim Rejections - 35 USC § 103

Claims 43-52 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson et al. (US 5,164,301) in view of Clark et al. (WO 98/53301) and Fisher Biotechnology Catalog (1995).

It is argued that Thompson et al. (US 5,164,301) only teach turbidity and fluorescence measurements in comparison to each other, not parallel measurements. It is argued that neither Thompson et al. nor Clark et al. teach the now claimed algorithm. It is urged that the instant algorithm allows accurate, sensitive and reliable analyses to be run. It is argued that Fisher Catalog does not remedy the deficiencies.

Thompson et al. teach measurement of drug sensitivity using both turbidity and fluorescence at example 5. The two measurements are compared to show that equivalent results are obtained. Thompson et al. teach identification of bacteria by fluorescent measurement in example 6. In both examples, a battery of tests may be run on the same multi-well microtiter tray to facilitate and improve reliability of the testing and analysis. It is stated at column 13 that the process can be automated and analyzed by a computer that has been appropriately programmed. Hence, contrary to the arguments in the response, Thompson et al. do teach turbidity for drug sensitivity, and fluorescence for identification.

It is not contested that Clark et al. teach turbidity for drug sensitivity, and fluorescence for identification. It is not contested that Fisher Catalog teaches a masked microtiter plate that meets the requirements of the claimed invention. It is contended that none of the references teaches using the claimed algorithm. It is asserted that this algorithm improves the sensitivity and accuracy of the measurements.

The algorithm in and of itself involves mental steps: a decision tree as to whether further incubation is necessary. The mental steps determine the sequence and actions of the automated process. The algorithm is actually needed for the efficient operation of the automated process. However, as noted in the Office action of 14 December 2001, automating a manual process is *prima facie* obvious for the known and expected advantages of improved efficiency, reliability, and cost-savings, *inter alia*. Automating allows running more tests on the same plate, even combining different types of tests as long as the machine can read the results. In the instant case the two types of results are both optical: turbidity in visible spectrum, and fluorescence. As pointed out in Thompson et al., the results can be interpreted by the computer with reference to a written code book, i.e., a database of results. The algorithm, which involves only mental steps, is not accorded patentable weight and does not make the automating or even simultaneous/parallel running of multiple assays unobvious.

The Rapid Gram Positive Procedural Manual is evidence that the equipment for automation was in currently available form at the time the alleged invention was made. All of the MIC and identification assays described in the Rapid Gram Positive Procedural Manual are fluorescent in nature, but other optical results would be just as easy to obtain.

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Applicant's arguments filed 18 April 2002 have been fully considered but they are not persuasive. The rejection under 35 USC 103 is adhered to for the reasons of record and the additional reasons above.

No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

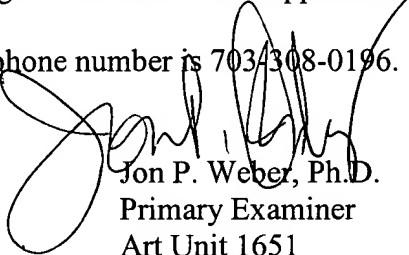
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
June 24, 2002